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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,964	09/08/2000	Meir Shinitzky	24259	9351

7590

01/15/2002

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EXAMINER

HUYNH, PHUONG N

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant(s)	SHINITZKY ET AL.	
	Application No.	09/555,964	
	Examiner	"Neon" Phuong Huynh	Art Unit
			1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 6-13 are pending.
2. In view of the amendment filed 11/5/01, only the following rejection remains.
3. Claims 6-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shinitzky *et al.* (WO 97/13152, PTO 1449, of record) in view of Kessler *et al.* (Demenita 6(6): 330-3; 1995; PTO 892, of record) and Burbaea *et al.* (ZH Nevropatol Psikhiatr IM S S Korsakova 86(1): 103-105; 1986, of record) for the same reasons set forth in Paper No 9.

Applicants' arguments filed 11/5/01 have been fully considered but are not found persuasive.

Applicants' position is that there is no suggestion or incentive that would motivate the skill artisan to modify the reference, there is no motivation to combine the references.

The WO 97/13152 publication teaches a diagnostic method comprising collecting blood from a number of individuals, isolating platelet from the said blood samples (See entire document, page 8 in particular), collecting the platelets and preparing platelet proteins by isoelectric focusing, (See page 10) wherein said proteins have a pI between 7 and 9 which anticipates the claimed pI about 6.5 as recited in claim 6 (See page 12, Fig 4). The reference platelet protein having a pI of 9 is above the claimed pI above about 6.5 as recited in claim 8. Claims 11-13 are included in this rejection because the term "about" expands the claimed pI to read on the reference pI of the platelet proteins and the claimed platelet proteins appear to be the reference platelet proteins.

The claimed invention as recited in claim differs from the reference only by the recitation of diagnosis of schizophrenia in an individual by determine a DTH reaction to the platelet proteins or fractions thereof having a pI of above 6.5.

The claimed invention as recited in claims 7 and 9 differs from the reference only by the recitation of injecting the platelet derived proteins or fractions thereof into a subject and examining the subject for the occurrence of delayed type hypersensitivity reaction at the site of injection, a positive result being a reaction above that which is observed in non-schizophrenic subjects, indicating that the subject has a high likelihood of being schizophrenic.

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The claimed invention as recited in claim 8 differs from the reference only by the recitation of obtaining a blood sample from a number of schizophrenic or non-schizophrenic individual.

Kessler *et al* teach platelets triggers autoimmune events which are apparently involved in schizophrenia (See page 330, column 1, first paragraph, in particular) and the numbers of platelet dense granules and platelet cell size in schizophrenic patients increased compared with healthy non-schizophrenic control (See Abstract, page 331, column 2, Table 1, in particular). Kessler *et al* further teach that the number of dense bodies per platelet in schizophrenic patients is relatively the same as the Alzheimer-type demented patient (See Tables 1 and 2, in particular) and the number of dense granules in platelets from schizophrenic and demented patients are significantly higher than non-schizophrenic young individual (See Table 1 and 2, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the neuroproteins as taught by Burbaea *et al* with the platelets proteins as taught by the WO 97/13152 publication and Kessler *et al* for a method of diagnosing schizophrenia by detecting a DTH reaction as taught by Burbaea *et al*. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Burbaea *et al*. teach the use of delayed type hypersensitivity reaction (DTH) for a diagnostic method for schizophrenia (See abstract in particular). Kessler *et al* teach platelets triggers autoimmune events which are apparently involved in schizophrenia (See page 330, column 1, first paragraph, in particular) and the numbers of platelet dense granules and platelet cell size in schizophrenic patients and demented patients increased compared with healthy non-schizophrenic control (See Table 1 and 2, in particular). The WO 97/13152 publication teaches platelet proteins having a pI between 7 and 9 are useful for a diagnostic method for dementia (See entire document, page 8 in particular).

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

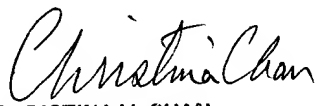
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
7. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

January 14, 2002


CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 1644